REMARKS

The amendment to the specification is merely a clarification of the existing text and does not represent new matter.

The amendments to claims 2-4 do not narrow the scope of those components as recited in independent claim 1. New claims 13-17 recite aspects of the invention and are fully supported by the specification.

An abstract of the invention is attached hereto.

The allegation that WO91/00095 ("Cohen") anticipates the claimed invention is unwarranted. The instant claims recite a method of "compensating for an absolute or relative testosterone deficiency..." The fact that the instant claims also recite "with simultaneous prophylaxis for the development of BPH or prostate cancer" does not obscure the fact that the claims also recite "a method of compensating for an absolute or relative testosterone deficiency." Cohen, however, provides no hint that the patients treated by its method exhibit such a testosterone deficiency, or that its method compensates for such a deficiency. The mere assertion by the Examiner that the patients of Cohen "inherently" suffer from a testosterone deficiency does not constitute proof that this is so. The failure of the reference to disclose such a testosterone deficiency is, in itself, sufficient reason why the reference does not anticipate the claimed invention. An anticipatory reference must disclose all the material elements of a claim (*In re Marshall*, 198 U.S.P.Q. 344 (CCPA 1978)).

Moreover, where inherent anticipation is alleged, the law requires that the reference "necessarily" and "inevitably" functions in accordance with the claimed method, *Verdegal Bros., Inc. v. Union Oil of California*, 2 U.S.P.Q. 1241 (Fed. Cir. 1986).

In fact, the disclosure of Cohen actually suggests that a testosterone deficiency is not inherent in its intended patients. The purpose of Cohen's method is male contraception (see, *e.g.*, Title and Abstract), *i.e.* a method to decrease sperm production (see, *e.g.*, page 7, lines 2-7). At page 14, lines 19-31, especially lines 24-26, Cohen states that the ability of its method to prevent prostate cancer is, in effect, merely an advantageous side-effect of it use in contraception ("This discovery [of the prostate cancer prevention effect] provides an important benefit to human males

who take the compositions of this invention as a contraceptive.") Cohen does not disclose or suggest that males in need of contraception -- the intended patients of its method -- suffer from a testosterone deficiency. In fact, just the opposite would be the norm.

Furthermore, Cohen does not render the instant claims obvious. Cohen provides no motivation to administer, *e.g.*, an androgen and a progestagen to male patients who suffer from an absolute or relative testosterone deficiency. Absent motivation, with the requisite reasonable expectation of success, to modify its method (administering the agents to patients in need of contraception) in order to achieve the instantly claimed method (administering the agents to a different class of patients, who are in need of compensation of a testosterone deficiency), the reference does not render the claims obvious. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991).

In view of the preceding arguments, the application is believed to be in condition for allowance, which action is respectfully requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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Attorney Docket No.: JENA-3

Date: September 17, 2001

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

Paragraph beginning at page 5, line 11 has been amended as follows:

--The object is achieved by the use according to the invention of combination preparations ~~according to claim 1~~ for compensating for an absolute and relative testosterone deficiency with simultaneous therapy of the benign prostatic hyerplasia (BPH). These contain a natural or synthetic androgen, and a gestagen, antigestagen, antiestrogen, GnRH analog, testosterone-5-α-reductase inhibitor, α-andreno-receptor blocker or phosphodiesterase inhibitor.--

IN THE CLAIMS

2. (Twice Amended) A method according to claim 1, wherein ~~the~~ a natural androgen ~~component~~ is administered which is testosterone, testosterone undecanoate, dehydroepiandrosterone, dehydroepiandrosterone sulfate, testosterone propionate, testosterone enanthate, testosterone buciclate, testosterone cypionate or androstene dione.

3. (Twice Amended) A method according to claim 1, wherein ~~the~~ a synthetic androgen ~~component~~ is administered which is 17-methyltestosterone, fluoxymesterone, danazol, mesterolone, nandrolone decanoate, nandrolone phenylpropionate, oxandrolone, oxymetholone, or stanazolol.

4. (Twice Amended) A method according to claim 1, wherein ~~the~~ a gestagen ~~component~~ is administered which is dienogest, levonorgestrel, gestodene, desogestrel, norgestimate, norethisterone, a norethisterone ester, levonorgestrel, progesterone, chloromadinone acetate, cyproterone acetate, medroxy progesterone acetate, megestrol acetate, dydrogesterone, trimegestone or nomegestrol.

Claims 13-17 have been added.

ABSTRACT

This invention relates to pharmaceutical combinations for compensating for an absolute and relative testosterone deficiency in men with simultaneous prophylaxis for the development of a benign prostatic hyperplasia (BPH) or prostate cancer. The combinations according to the invention contain a natural or synthetic androgen in combination with a gestagen, an antigestagen, an antiestrogen, a GnRH analog, a testosterone-5α-reductase inhibitor, an α-andreno-receptor blocker or a phosphodiesterase inhibitor. In comparison to the combinations according to the invention, any active ingredient by itself cannot achieve the desired goal.